

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: De Francesco et al.

Serial No. \_\_\_\_\_

Filed: \_\_\_\_\_

For: METHOD FOR REPRODUCING IN VITRO THE  
RNA-DEPENDENT RNA POLYMERASE AND TERMINAL  
NUCLEOTIDYL TRANSFERASE ACTIVITIES ENCODED BY  
HEPATITIS C VIRUS (HCV)

Art Unit: \_\_\_\_\_

Examiner: \_\_\_\_\_

10979 U.S. PTO  
10/085476  
02/27/02

Assistant Commissioner for Patents  
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application.

This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

## EXPRESS MAIL CERTIFICATE

DATE OF DEPOSIT Feb 27 2002  
EXPRESS MAIL NO. EL523911587US

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS  
BEING DEPOSITED WITH THE UNITED STATES POSTAL  
SERVICE AS EXPRESS MAIL "POST OFFICE TO  
ADDRESSEE" BEFORE 5 P.M. ON THE ABOVE DATE IN  
AN ENVELOPE ADDRESSED TO ASSISTANT COMMISSIONER  
FOR PATENTS, WASHINGTON, D.C. 20231.

MAILED BY Christine Cuffe  
DATE 2-27-02

Thereby certify that this correspondence is being deposited with  
the United States Postal Service as first class mail in an envelope  
addressed to: Assistant Commissioner for Patents, Washington,  
D.C. 20231, on the date appearing below.

MERCK &amp; CO., INC.

By \_\_\_\_\_ Date \_\_\_\_\_

# INFORMATION DISCLOSURE STATEMENT

jc979 U.S. PTO  
10/085476  
02/27/02

4. Copies of the references listed on the attached form are not enclosed because they have been submitted or cited by the Office in a related application as follows:

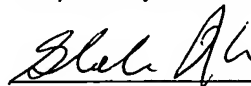
RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE
08/952,981	March 23, 1998	IT0002P

upon which the instant application relies for an earlier filing date under 35 U.S.C. 120. Therefore, pursuant to 37 C.F.R. 1.98(d), copies of these references are not enclosed herewith. If this is inconvenient, additional copies will be submitted upon request.

5. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to a first Official Action on the merits.
- ☐ the attached information is being filed more than three months after the filing date and after receipt of the first Office Action on the merits, but before Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of the statement.

Respectfully submitted,



By: Sheldon O. Heber

Attorney \_\_\_\_\_ For Applicant(s)

Reg. No. 38,179

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594- 1958

Date: 2/27/02

### COMPLETE OF KNOWN

**Application Number****Filing Date****First Named Inventor**

De Francesco et al.

Group Art Unit

Examiner Name

*(use as many sheets as necessary)*

Sheet

1

of

2

Attorney Docket Number

IT0002PCA

jc979 U.S. PRO  
10/085476  
02/27/02

[illegible][illegible]

Examiner  
Signature

Date  
Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.

Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc. 10/05/2001

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE****STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**COMPLETELY KNOWN**

Application Number	
Filing Date	
First Named Inventor	De Francesco et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number	IT0002PCA

Sheet

2

of

2

**OTHER NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Al et al., Expression and characterization of the NS5B (RNA-dependent RNA polymerase) gene of hepatitis C virus, Hepatology, Vol. 22, No. 4 Pt. 2, pp 331A, 1995.
		Tomei et al., NS3 is a serine protease required for processing of hepatitis C virus polyprotein, J. of Virology, Vol. 67, No. 7, pps 4017-4026, 1993.
		Bartenschlager et al., Kinetic and structural analyses of hepatitis C virus polyprotein processing, J. of Virology, Vol. 68, No. 8, pps 5045-5055, 1994.
		Lin et al., Hepatitis C virus NS3 serine proteinase trans-cleavage requirements and processing kinetics, J. of Virology, Vol. 68, No. 12, pps 8147-8157, 1994.
		Miller et al., Hepatitis C virus shares amino acid sequence similarity with pestiviruses and flaviviruses as well as members of two plant virus supergroups, Proc. Natl. Acad. Sci. USA, Vol. 87, pps 2057-2061, 1990.
		Behrens et al., Identification and properties of the RNA-dependent RNA polymerase of hepatitis C virus, The EMBO Journal, Vol. 15, No. 1, pps 12-22, 1996.
		Bartholomeusz et al., Use of a flavivirus RNA-dependent RNA polymerase assay to investigate the antiviral activity of selected compounds, Antiviral Research, Vol. 24, pps 341-350, 1994.
		Grun et al., Dissociation of NS5 from cell fractions containing west nile virus-specific polymerase activity, Journal of Virology, Vol. 61, No. 11, pps 3641-3644, 1987.
		Chu et al., Characterization of kunjin virus RNA-dependent RNA polymerase: reinitiation of synthesis in vitro, Virology, Vol. 157, pps 330-337, 1987.
		Grun et al., Characterization of west nile virus RNA-dependent RNA polymerase and cellular terminal adenylyl and uridylyl transferase in cell-free extracts, Journal of Virology, Vol. 60, No. 3, pps 1113-1124, 1986.
		Bartholomeusz et al., Synthesis of dengue virus RNA in vitro: initiation and the involvement of proteins NS3 and NS5, Arch Virol, Vol. 128, pps 111-121, 1993.
		Lohmann et al., Biochemical properties of hepatitis C virus NS5B RNA-dependent RNA polymerase and identification of amino acid sequence motifs essential for enzymatic activity, Journal of Virology, Vol. 71, No. 11, pps 8416-8428, 1997.

Examiner  
SignatureDate  
Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.